Environmental Assessment for the Color Additive Petition to Permanently List FD&C Blue No. 2, Aluminum Lake for Use in Boneloc Bone Cement (CAP No. 2C0239)

1. **Date:** 20 July 1992

2. **Name of Petitioner:** Biomet, Inc.

3. **Address:** Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46580

4. **Description of Proposed Action**

The petitioner submits this Environmental Assessment pursuant to 21 CFR, section 25.31a(a) of the Federal Food, Drug, and Cosmetics Act, for the color additive **FD & C Blue No. 2 Aluminum Lake,** for the use in (Boneloc) Bone Cement. FD&C Blue No. 2, Aluminum Lake is provisionally listed for use in

Biomet, Inc., does not produce color additives. The product, Boneloc Bone Cement, is manufactured by:

Polymers Reconstructive A/S
Rugmarken 24-26,
DK-3520 Farum, Denmark

The color additive, FD & C Blue No. 2, Aluminum Lake is produced by:

BASF Farben + Fasern AG
Postfach 30 02 09
D-7000 Stuttgart 30 (Feuerbach), Germany

The responses in this environmental assessment are based on an estimated annual production of 8 lbs. of FD&C Blue No. 2, Aluminum Lake for use in bone cement. Approximately 992 lbs. of FD&C Blue No. 2, Aluminum Lake was certified in 1984 for use in foods and ingested drugs and for use in surgical suture by BASF Farben + Fasern AG, in Germany.

It is anticipated that FD&C Blue No. 2, Aluminum Lake will be used in very small amounts in bone cement in the United States. Due to the very small amount produced and used in bone cement, and the wide distribution of these small amounts, the amounts entering the environment will be immeasurable.

5. Identification of chemical substances that are the subject of the proposed action

a. **Name of Color Additive (see Appendix, for detail spec.)**
FD & C Blue #2, Aluminum Lake

b. Chemical Identity
Aluminum Hydroxide of Indigo Disulfonic acid,
$C_{16}H_{10}N_2O_8S_2 \times Al(OH)_3$

c. **Composition**
16-18% pure dye
10-20% volatile components at 110°C
(water)
Aluminum hydroxide as substrate

d. **Physical Properties**
Blue powder, Color Index of 73015:1
particle size: min. 95% $\leq$ 10 um
min. 50% $\leq$ 3 um

e. **Chemical Properties**
Insoluble in water and organic solvents,
Soluble in alkalis and acids

f. **Biological Properties**
FD & C Blue No.2 Aluminum Lake is an inert material that is biologically inactive.

g. **Specifications prescribing its component(s)**
Each batch of FD & C Blue No. 2, Aluminum Lake is certified, and meets specifications listed in:
21 CFR 74.1102(b)
Color Index 73025:1
C.A.S. No. 16521-38-3
EEC No. E 132

h. **Byproducts (identifying and limiting)**
The material meets FDA requirements that are listed in: 21 CFR 74.1102, and there are no new byproducts.

i. **Impurities**
None

j. **List of all substances used in production**
The following substances are used for producing this lake: FD & C Blue No. 2, aluminum sulfate, sodium carbonate, and water. We then get a precipitation of aluminum hydroxide, where the color (FD & C Blue No. 2) is absorbed.

6. Introduction of substances into the environment

6.1 Substances expected to be emitted

a. Air emissions

1. Water vapor
2. CO_2

b. Water emissions

1. FD&C Blue No. 2, Aluminum Lake
2. Water

c. Land emissions

1. None measurable

6.2 Controls employed

a. Air emissions

1. Dust collection methods are used to control materials in the air.

b. Water emissions

1. Liquid wastes containing FD&C Blue No.2, Aluminum Lake are screened to retrieve the optimum amount of colorant, then the water is passed through a purification system for re-use.

c. Land emissions

1. The are no solid waste materials that are produced that necessitate disposal.

6.3 Citation of, and statement of compliance with applicable emissions requirements (including occupational) at Federal, State and local levels.

The product used complies with the following legal regulations including all of the latest amendments:

- EEC council directive on food colours 1962
- EEC directive on pharmaceutical colours 1977
- EEC directive on cosmetics 1976
- Zusatzstoffverkehrsordnung 1984 (Germany)
- Arzneimittelfarbstoffverordnung 1982 (Germany)
- Kosmetikverordnung 1985 (Germany)
- FDA regulations according to CFR 21, ss 82.51

6.4 The effect approval will have on compliance with current emission requirements at production sites.

The approval of FD&C Blue No. 2, Aluminum Lake for use in Boneloc bone cement is not expected to result in the construction or operation of additional facilities, The manufacture of FD&C Blue No. 2, Aluminum Lake for use in Boneloc bone cement is not expected to affect compliance with current emission requirements.

6.5 Estimates of the quantities of substances expected to enter the environment as the result of the use and disposal of FD&C Blue No. 2, Aluminum Lake.

The estimates in this section are based on the annual manufacture of (8) eight pounds of FD&C Blue No. 2, Aluminum Lake for use in production of 50,000 units of Boneloc bone cement.

7. The fate of emitted substances in the environment

7.1 Air

a. Water vapor

Released water vapor is expected to disperse

b. CO_2

The small amount of CO_2 released is expected to disperse.

7.2 Water- freshwater, estuarine and marine ecosystems

a. water

Released water is not expected to affect aquatic ecosystems.

7.3 Land emission- terrestrial ecosystems

There are no emitted substances that will effect the terrestrial ecosystems.

8. The environmental effects of released substances.

The study described in the appendix section demonstrates that FD&C Blue No. 2, Aluminum Lake is not toxic. The results of complete biological and toxicology testing were reviewed and conclusions were reported in the Federal Register (48 FR, 5259, No. 25, Feb. 04, 1983), (copy enclosed in appendix). Because the color additive is not toxic, it is highly unlikely that significant environmental effects would result from the use of FD&C Blue No. 2, Aluminum Lake in Boneloc bone cement.

8.1 Air emissions

There are no anticipated environmental effects from substances released into air from production or use of FD&C Blue No. 2, Aluminum Lake. The emitted materials released are in such small amounts that it makes environmental effects highly unlikely. Furthermore, the emissions are expected to be non-toxic at the anticipated emission concentrations.

8.2 Water emissions

There are no anticipated environmental effects from substances released into water from production or use of FD&C Blue No. 2, Aluminum Lake. The emitted materials released are screened as well as processed through a water purification system that it makes environmental effects highly unlikely. Furthermore, the emissions are expected to be non-toxic at the anticipated emission concentrations.

8.3 Land emissions

There are no anticipated environmental effects from substances released onto land from production or use of FD&C Blue No. 2, Aluminum Lake. The emitted materials released are in such small amounts that it makes environmental effects highly unlikely. Furthermore, the emissions are expected to be non-toxic at the anticipated emission concentrations.

9. Use of natural resources and energy

9.1 Natural resources required to produce, transport, and dispose of FD&C Blue No. 2, Aluminum Lake.

It is estimated that the production of (8) lbs. of FD&C Blue No.2, Aluminum Lake, per year, for use in Boneloc bone cement will not result in any measurable increase in kilowatt-hours of electricity, pounds of steam, or cubic feet of natural gas usage.

The energy used to transport and dispose of FD&C Blue No. 2, Aluminum lake and its wastes is considered insignificant.

9.2 Effects on endangered or threatened species, or on property listed in the National Register of Historic Places.

The approval of FD&C Blue No. 2, Aluminum Lake for use in Boneloc bone cement is not expected to affect endangered or threatened species, or property listed in the National Register of Historic Places.

10. Mitigation measures

No adverse environmental effects are expected to be associated with the approval of FD&C Blue No. 2, Aluminum Lake for use in Boneloc bone cement. Therefore, mitigation measures are not necessary.

11. Alternatives to the proposed action

No adverse environmental affects are expected to be associated with the approval of FD&C Blue No. 2, Aluminum Lake for use in Boneloc Bone Cement. Therefore, alternative to the proposed action are not necessary. It is not necessary to examine the risks and benefits of the proposed action because there are no identifiable environmental effects.

12. List of preparers

W. Dutch Harrison, MBA
Airport Industrial Park
Clinical Affairs
Warsaw, Indiana 46581

13. The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

Name

7/20/92
Date